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DEPARTMENT OF HEALTH & HUMAN SERVICES

10/8/97 RB

Certified/Return Receipt Requested

Food and Drug Administration
Kansas City District Office
11630 West 80th Street
P.O. Box 15905
Lenexa, Kansas 66285-5905

Telephone: (913) 752-2100

October 6, 1997

WARNING LETTER

James R. Smith, President/CEO
Southwest Technologies, Inc.
1746 Levee Road
North Kansas City, MO 64116

Ref.# - 98-KAN-001

Dear Mr. Smith:

During an inspection of your firm located in North Kansas City, Missouri, on June 23 through July 11, 1997, our investigator determined that your firm manufactures sterile wound dressings. Sterile wound dressings are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (Act).

The above-stated inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the current good manufacturing practice (CGMP) requirement of the Quality System Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, to include, but not limited to, the following:

1. Failure to maintain acceptable validations for the [redacted] hot air sealing machine to produce intact seals consistently, and for the automated gel dispensing machine. For example, a review of 26 device history records revealed 5 lots which were 100% inspected, and had finished sterile devices with unsatisfactory seals [21 CFR 820.61]. This would also be a violation of the Quality System Regulation, 21 CFR 820.70(g), 820.75(a) and 820.75(b).

2. Failure to control the release of finished devices that have not met all of your specifications; failure to investigate non-conforming devices; and failure to routinely document the disposition of non-conforming devices. For example, you are distributing devices which do not meet their acceptance criteria, that have been "labeled" as "seconds" [21 CFR 820.160]. This would also be a violation of the Quality System Regulation, 21 CFR 820.80(d) and 820.90(b)(1).

DISTRIBUTION:
Orig.: Addressee
bcc: LF; FF(1929833); HFA-224; HFZ-300; HFI-35/DIB(via FOI); HFC-210; HFC-240(MPQAS); RRW; RF

CRP:jl

criteria, that have been "labeled" as "seconds" [21 CFR 820.160]. This would also be a violation of the Quality System Regulation, 21 CFR 820.80(d) and 820.90(b)(1).

3. Failure to maintain most current and complete Standard Operating Procedures in production areas [21 CFR 820.100]. This would also be a violation of the Quality System Regulation, 21 CFR 820.40(a) and 820.70(a).

4. Failure to maintain documented procedures that are adequate to ensure purchased components conform to required specifications [21 CFR 820.80]. This would also be a violation of the Quality System Regulation, 21 CFR 820.50 and 820.80.

At the conclusion of the inspection Form FDA 483, Inspectional Observations, was prepared, issued to and discussed with you.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA 483 issued at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

We acknowledge that you have submitted to this office a response concerning our investigator's observations noted on the Form FDA 483. We have reviewed your response and have concluded that it is inadequate as follows:

1. Observation 4 - there is still no justification for your selection of Mil Std. 105E at a sampling level of II and an A.Q.L. of 1.5.

2. Observations 7 & 9 - there is no indication that steps have been taken to correct your document control system, which allowed the placement of outdated procedures in the production area.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for devices to which the GMP deficiencies are reasonably related will be cleared until the

violations have been corrected. Also, no requests for Certificates For Products For Export will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to Clarence R. Pendleton, Compliance Officer, at the above address.

Sincerely,

W. Michael Rogers
District Director
Kansas City District